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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,640	12/31/2001	Frank E. Manning	1275.37US01	5821

7590 02/09/2005

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EXAMINER

HAN, MARK K

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,640

Applicant(s)

MANNING ET AL.

Examiner

Mark K Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 13-17 and 24-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to claim 13 requires the inner guide to have a stiffness less than that of the outer guide. See line 8 of claim 13. The originally filed application does not disclose any such limitation, explicitly or implicitly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 5-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,562,049 to Norlander et al. (hereinafter "Norlander") in view of U.S. Patent

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No. 5,454,790 to Dubrul, further in view of U.S. Patent No. 4,586,923 to Gould et al. (hereinafter "Gould").

Norlander discloses a medical introducer apparatus, for accessing the coronary sinus, having proximal and distal ends comprising an outer guide (11) having an open lumen (26) and a longitudinal pre-stress line (46, 59) extending between a distal end and a proximal end of the outer guide, see Figure 12; an inner guide (12) having an open lumen (25), the inner guide movably disposed within the open lumen of the outer guide such that the inner guide can rotate axially and translate longitudinally relative to the outer guide, see Column 5, line 64 through Column 6, line 49, and Column 8, line 64 through Column 9, line 2, the inner guide having a generally straight shaft (19) or include preformed bends that approximate those found in the outer introducer sheath, it may be advantageous for the inner guide to include a distal curved portion (17) to facilitate access of a particular vessel or duct, see Column 6, lines 32-43; and a guide handle (21, 22, 23) having a proximal end (23) connected to the proximal end of the outer guide, the guide handle separable into at least two sections such that guide handle separation splits the outer guide along the longitudinal pre-stress line at the proximal end of the outer guide, see Column 8, lines 29-38, the outer guide further splitting along the longitudinal pre-stress line upon outer guide retraction in a proximal direction relative to the inner guide; and wherein the distal ends of both the outer guide and inner guide include an occlusion device (49), see Column 9, line 41 through Column 10, line 62 and Column 12, line 44 through Column 13, line 32.

Norlander also discloses that

Norlander fails to disclose the guide handle having a distal end connected to the proximal end of the outer guide.

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Dubrul discloses an apparatus for catheterization access having proximal and distal ends comprising an outer guide (110, 114) having an open lumen (not shown) and a longitudinal pre-stress line (136) extending between a distal end and a proximal end of the outer guide, see Figure 19 and 21-23; an inner guide (80) having an open lumen (not shown), the inner guide movably disposed within the open lumen of the outer guide such that the inner guide can rotate axially and translate longitudinally relative to the outer guide, see Column 8, lines 41-64; and a guide handle (134, 84), the guide handle separable into at least two sections such that guide handle separation splits the outer guide along the longitudinal pre-stress line at the proximal end of the outer guide, see Column 7, lines 64-66, Column 8, lines 38-40, and Column 8, lines 57-64, the outer guide further splitting along the longitudinal pre-stress line upon outer guide retraction in a proximal direction relative to the inner guide.

It would have been a matter of obvious design choice to one having ordinary skill in the art to have modified Norlander's guide handle so as to have a distal end connected to the proximal end of the outer guide as taught by Dubrul, as an equivalent alternative. Applicant has not disclosed that having the guide handle's distal end as the point of connection to the outer guide's proximal end solves any stated problem or is for any particular purpose. Moreover, it appears that the guide handle would perform equally well with the guide handle's proximal end as the point of connection to the outer guide's proximal end, i.e. Norlander's arrangement. Accordingly, the use of a distal end connection is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Norlander in view of Dubrul, as both connections are obvious alternatives in view of each other.

Norlander in view of Dubrul disclose the invention as claimed with the exception of a steering tendon disposed within the outer guide, a distal end of the steering tendon connected to the distal end of the outer guide, such that the steering tendon deflects the distal end of the outer guide upon application of a tensile force to a proximal end of the steering tendon, further comprising a steering mechanism connected to the proximal end of the steering tendon, the steering mechanism applying a tensile force to the proximal end of the steering tendon, wherein the steering mechanism is connected to the guide handle; and wherein the steering mechanism includes a steering handle pivotably mounted to the guide handle.

Gould discloses a curving tip catheter (10) comprising an outer guide (12) having an open lumen (24) and a guide handle (40) having a distal end (44) connected to the proximal end of the outer guide (20), a steering member having a tendon (60) disposed within the outer guide, a distal end (62) of the steering tendon connected to the distal end (30) of the outer guide, such that the steering tendon deflects the distal end of the outer guide upon application of a tensile force to a proximal end (64) of the steering tendon, see Figure 1, further comprising a steering mechanism (100) connected to the proximal end of the steering tendon, the steering mechanism applying a tensile force to the proximal end of the steering tendon, wherein the steering mechanism is connected to the guide handle; and wherein the steering mechanism includes a steering handle (102) pivotably mounted to the guide handle, see Figure 5.

It would have been obvious to one having ordinary skill in the art to have modified Norlander in view of Dubrul's guiding catheter with the steering mechanism as taught by Gould, so as to adapt the guiding catheter to be in to be inserted into and through the lumen of a blood

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vessel in a network of branching blood vessels in a body and is manipulatable therethrough to a desired blood vessel branch within the network of branching blood vessels.

3. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norlander, Dubrul and Gould as applied to claim 1 above, and further in view of U.S. Patent No. 4,952,359 to Wells.

Norlander, Dubrul and Gould disclose the invention as claimed with the exception of the longitudinal pre-stress line comprising two longitudinal pre-stress lines defined as two V-shaped notches situated on opposite surfaces of the outer guide.

Wells discloses a splittable catheter comprising an outer guide (11) having an open lumen (11b) and two longitudinal pre-stress lines (11a) in the form of V-shaped notches situated on opposite surfaces of the outer guide.

It would have been obvious to one having ordinary skill in the art to have modified Norlander, Dubrul and Gould's longitudinal pre-stress lines with V-shaped notches situated on opposing sides of the outer guide as taught by Wells, so as to create a splittable guide catheter made of high strength material which exhibits the requisite circumferential resistance (i.e. hoop strength) even though areas of weakness extend from the tip of the catheter longitudinally up the catheter body, which afford the device the ability to be removed with the application of a relatively low shear tear force.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norlander, Dubrul and Gould as applied to claim 1 above, and further in view of U.S. Patent No. 6,002,956 to Schaer.

Norlander, Dubrul and Gould disclose the invention as claimed with the exception of at least one electrode on the distal end of one or both of the inner guide and outer guide; and at least one electrical conductor coupled to the at least one electrode, the at least one conductor disposed within one or both of the inner guide and outer guide.

Schaer discloses an over-the-wire electrophysiology catheter, comprising an outer/inner guide (10) having an open lumen (34); and an electrode (18) on the distal end (12) of the outer/inner guide; and a conductor (16) disposed within the outer/inner guide.

It would have been obvious to one having ordinary skill in the art to have modified Norlander, Dubrul and Gould's guiding catheter with an outer/inner guide with integral sensing electrodes, as taught by Schaer, so as to enable detection of electrical activity or signals within a patient's heart, thus facilitating treatment thereof.

5. Claims 13, 17, 24-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norlander, Dubrul and Gould as applied to claim 1 above, and further in view of U.S. Patent No. 6,408,214 to Williams et al. (hereinafter "Williams").

Norlander, Dubrul and Gould disclose the claimed invention as shown above. Norlander, Dubrul and Gould, however, do not disclose that the outer sheath is stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Norlander, Dubrul and Gould by making the outer sheath stiffer than the inner sheath in order to enhance torqueability of the catheter.

6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norlander, Dubrul, Gould and Wells as applied to claims 2-4 above, and further in view of Williams.

Norlander, Dubrul, Gould and Wells disclose the claimed invention as shown above.

Norlander, Dubrul, Gould and Wells, however, do not disclose that the outer sheath is stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Norlander, Dubrul, Gould and Wells by making the outer sheath stiffer than the inner sheath in order to enhance torqueability of the catheter.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norlander, Dubrul, Gould and Schaer as applied to claim 10 above, and further in view of Williams.

Norlander, Dubrul, Gould and Schaer disclose the claimed invention as shown above.

Norlander, Dubrul, Gould and Schaer, however, do not disclose that the outer sheath is stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Norlander, Dubrul, Gould and Schaer by making the outer sheath stiffer than the inner sheath in order to enhance torqueability of the catheter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 5-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 12 and 14 of copending Application No. 10/041,911 in view of Dubrul and further in view of Gould.

The application's claims merely add a feature, i.e. the guide handle separable into at least two sections such that guide handle separation splits the outer guide, absent from the patented claims.

Dubrul discloses an apparatus for catheterization access having proximal and distal ends comprising an outer guide (110, 114) having an open lumen (not shown) and a longitudinal pre-stress line (136) extending between a distal end and a proximal end of the outer guide, see Figure 19 and 21-23; an inner guide (80) having an open lumen (not shown), the inner guide movably disposed within the open lumen of the outer guide such that the inner guide can rotate axially and translate longitudinally relative to the outer guide, see Column 8, lines 41-64; and a guide handle (134, 84), the guide handle separable into at least two sections such that guide handle separation splits the outer guide along the longitudinal pre-stress line at the proximal end of the outer guide, see Column 7, lines 64-66, Column 8, lines 38-40, and Column 8, lines 57-64, the outer guide further splitting along the longitudinal pre-stress line upon outer guide retraction in a proximal direction relative to the inner guide.

It would have been obvious to one having ordinary skill in the art to have modified the patented claims to positively recite a separable guide handle at the proximal end of the outer guide, as taught by Dubrul, so as to provide a grippable surface which would enable the user to

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readily grasp the proximal end of the outer guide and thus facilitate the removal of the outer guide.

The application's claims in view of Dubrul render obvious the claims as recited with the exception of the steering mechanism including a steering handle pivotably mounted to the guide handle, absent from the patented claims.

Gould discloses a curving tip catheter (10) comprising an outer guide (12) having an open lumen (24) and a guide handle (40) having a distal end (44) connected to the proximal end of the outer guide (20), a steering tendon (60) disposed within the outer guide, a distal end (62) of the steering tendon connected to the distal end (30) of the outer guide, such that the steering tendon deflects the distal end of the outer guide upon application of a tensile force to a proximal end (64) of the steering tendon, see Figure 1, further comprising a steering mechanism (100) connected to the proximal end of the steering tendon, the steering mechanism applying a tensile force to the proximal end of the steering tendon, wherein the steering mechanism is connected to the guide handle; and wherein the steering mechanism includes a steering handle (102) pivotably mounted to the guide handle, see Figure 5.

It would have been obvious to one having ordinary skill in the art to have modified the patented claims in view of Dubrul to positively recite the steering mechanism including a steering handle pivotably mounted to the guide handle, as taught by Gould, so as to adapt the guiding catheter to be inserted into and through the lumen of a blood vessel in a network of branching blood vessels in a body and is manipulatable therethrough to a desired blood vessel branch within the network of branching blood vessels.

This is a provisional obviousness-type double patenting rejection.

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9. Claims 2-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 12 and 14 of copending Application No. 10/041,911 in view of Dubrul and Gould as applied to claim 1 above further in view of Wells.

The application's claims in view of Dubrul and Gould render obvious the claims as recited with the exception of the longitudinal pre-stress line comprising two longitudinal pre-stress lines defined as two V-shaped notches situated on opposite surfaces of the outer guide, absent from the patented claims.

Wells discloses a splittable catheter comprising an outer guide (11) having an open lumen (11b) and two longitudinal pre-stress lines (11a) in the form of V-shaped notches situated on opposite surfaces of the outer guide.

It would have been obvious to one having ordinary skill in the art to have modified the patented claims in view of Dubrul and Gould to positively recite longitudinal pre-stress lines with V-shaped notches situated on opposing sides of the outer guide, as taught by Wells, so as to create a splittable guide catheter made of high strength material which exhibits the requisite circumferential resistance (i.e. hoop strength) even though areas of weakness extend from the tip of the catheter longitudinally up the catheter body, which afford the device the ability to be removed with the application of a relatively low shear tear force.

This is a provisional obviousness-type double patenting rejection.

10. Claims 13, 17, 24-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 12 and 14 of

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copending Application No. 10/041,911 in view of Dubrul and Gould as applied to claim 1 above, and further in view of Williams.

The application's claims in view of Dubrul and Gould render obvious the claims as recited with the exception of the outer sheath being stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Dubrul and Gould by making the outer sheath stiffer than the inner sheath, as suggested by Williams, in order to enhance torqueability of the catheter.

This is a provisional obviousness-type double patenting rejection.

11. Claims 14-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 12 and 14 of copending Application No. 10/041,911 in view of Dubrul, Gould and Wells as applied to claims 2-4 above further in view of Williams.

The application's claims in view of Dubrul, Gould and Wells render obvious the claims as recited with the exception of the outer sheath being stiffer than the inner sheath.

Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Dubrul, Gould and Wells by making the outer sheath stiffer than the inner sheath, as suggested by Williams, in order to enhance torqueability of the catheter.

This is a provisional obviousness-type double patenting rejection.

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12. Claims 1 and 5-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,755,812 in view of Norlander in view of Dubrul, further in view of Gould.

The application's claims merely add features, i.e., a longitudinal pre-stress line extending between the proximal and distal ends of the outer guide; a guide handle having a distal end connected to the proximal end of the outer guide, the guide handle separable into at least two sections such that guide handle separation splits the outer guide; and an occlusion device connected to a distal end of the inner guide, absent from the patented claims.

Norlander discloses a medical introducer apparatus, for accessing the coronary sinus, having proximal and distal ends comprising an outer guide (11) having an open lumen (26) and a longitudinal pre-stress line (46, 59) extending between a distal end and a proximal end of the outer guide, see Figure 12; an inner guide (12) having an open lumen (25), the inner guide movably disposed within the open lumen of the outer guide such that the inner guide can rotate axially and translate longitudinally relative to the outer guide, see Column 5, line 64 through Column 6, line 49, and Column 8, line 64 through Column 9, line 2, the inner guide having a generally straight shaft (19) or include preformed bends that approximate those found in the outer introducer sheath, it may be advantageous for the inner guide to include a distal curved portion (17) to facilitate access of a particular vessel or duct, see Column 6, lines 32-43; and a guide handle (21, 22, 23) having a proximal end (23) connected to the proximal end of the outer guide, the guide handle separable into at least two sections such that guide handle separation splits the outer guide along the longitudinal pre-stress line at the proximal end of the outer guide, see Column 8, lines 29-38, the outer guide further splitting along the longitudinal pre-stress line

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upon outer guide retraction in a proximal direction relative to the inner guide; and wherein the distal ends of both the outer guide and inner guide include an occlusion device (49), see Column 9, line 41 through Column 10, line 62 and Column 12, line 44 through Column 13, line 32.

It would have been obvious to one having ordinary skill in the art to have modified the patented claims to positively recite a longitudinal pre-stress line extending between the proximal and distal ends of the outer guide, as well as an occlusion device connected to a distal end of the inner guide, as taught by Norlander, so as to enable removal of the outer guide and/or inner guide relative to the position-dependent device being delivered via the guide catheter, such as in the case of placement of devices such as a pacemaker and defibrillator leads; as well as to provide a means of temporarily occluding the vessel while contrast media is injected to improve fluoroscopic guidance of the device to the target site.

Further the patented claims in view of Norlander render obvious the claims as recited with the exception of the guide handle having a distal end connected to the proximal end of the outer guide, absent from the patented claims.

Dubrul discloses an apparatus for catheterization access having proximal and distal ends comprising an outer guide (110, 114) having an open lumen (not shown) and a longitudinal pre-stress line (136) extending between a distal end and a proximal end of the outer guide, see Figure 19 and 21-23; an inner guide (80) having an open lumen (not shown), the inner guide movably disposed within the open lumen of the outer guide such that the inner guide can rotate axially and translate longitudinally relative to the outer guide, see Column 8, lines 41-64; and a guide handle (134, 84), the guide handle separable into at least two sections such that guide handle separation splits the outer guide along the longitudinal pre-stress line at the proximal end of the outer guide,

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see Column 7, lines 64-66, Column 8, lines 38-40, and Column 8, lines 57-64, the outer guide further splitting along the longitudinal pre-stress line upon outer guide retraction in a proximal direction relative to the inner guide.

It would have been a matter of obvious design choice to one having ordinary skill in the art to have modified the patented claims in view of Norlander to positively recite a guide handle with a distal end connected to the proximal end of the outer guide as taught by Dubrul, as an equivalent alternative. Applicant has not disclosed that having the guide handle's distal end as the point of connection to the outer guide's proximal end solves any stated problem or is for any particular purpose. Moreover, it appears that the guide handle would perform equally well with the guide handle's proximal end as the point of connection to the outer guide's proximal end, i.e. Norlander's arrangement. Accordingly, the use of a distal end connection is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Norlander et al. in view of Dubrul, as both connections are obvious alternatives in view of each other.

The application's claims in view of Norlander and Dubrul render obvious the claims as recited with the exception of the steering mechanism connected to the guide handle and including a steering handle pivotably mounted to the guide handle, absent from the patented claims.

Gould discloses a curving tip catheter (10) comprising an outer guide (12) having an open lumen (24) and a guide handle (40) having a distal end (44) connected to the proximal end of the outer guide (20), a steering tendon (60) disposed within the outer guide, a distal end (62) of the steering tendon connected to the distal end (30) of the outer guide, such that the steering tendon deflects the distal end of the outer guide upon application of a tensile force to a proximal end

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(64) of the steering tendon, see Figure 1, further comprising a steering mechanism (100) connected to the proximal end of the steering tendon, the steering mechanism applying a tensile force to the proximal end of the steering tendon, wherein the steering mechanism is connected to the guide handle; and wherein the steering mechanism includes a steering handle (102) pivotably mounted to the guide handle, see Figure 5.

It would have been obvious to one having ordinary skill in the art to have modified the patented claims in view of Norlander and Dubrul to positively recite the steering mechanism connected to the guide handle and including a steering handle pivotably mounted to the guide handle, as taught by Gould, so as to adapt the guiding catheter to be inserted into and through the lumen of a blood vessel in a network of branching blood vessels in a body and is manipulatable therethrough to a desired blood vessel branch within the network of branching blood vessels.

13. Claims 2-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,755,812 in view of Norlander, Dubrul and Gould, further in view of Wells.

The application's claims in view of Norlander, Dubrul and Gould render obvious the claims as recited with the exception of the longitudinal pre-stress line comprising two longitudinal pre-stress lines defined as two V-shaped notches situated on opposite surfaces of the outer guide, absent from the patented claims.

Wells discloses a splittable catheter comprising an outer guide (11) having an open lumen (11b) and two longitudinal pre-stress lines (11a) in the form of V-shaped notches situated on opposite surfaces of the outer guide.

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It would have been obvious to one having ordinary skill in the art to have modified the patented claims in view of Norlander, Dubrul and Gould to positively recite longitudinal pre-stress lines with V-shaped notches situated on opposing sides of the outer guide, as taught by Wells, so as to create a splittable guide catheter made of high strength material which exhibits the requisite circumferential resistance (i.e. hoop strength) even though areas of weakness extend from the tip of the catheter longitudinally up the catheter body, which afford the device the ability to be removed with the application of a relatively low shear tear force.

14. Claims 13, 17 and 24-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,755,812 in view of Norlander, Dubrul and Gould, further in view of Williams.

The application's claims in view of Norlander, Dubrul and Gould render obvious the claims as recited with the exception of the outer sheath being stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2, lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Norlander, Dubrul and Gould by making the outer sheath stiffer than the inner sheath, as suggested by Williams, in order to enhance torqueability of the catheter.

15. Claims 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,755,812 in view of Norlander, Dubrul, Gould and Wells as applied to claims 2-4 above, further in view of Williams.

The application's claims in view of Norlander, Dubrul, Gould and Wells render obvious the claims as recited with the exception of the outer sheath being stiffer than the inner sheath. Williams suggests an outer sheath having a stiffness greater than the inner sheath. See col. 2,

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lines 9-13. It would have been obvious to one of ordinary skill in the art to modify the invention of Norlander, Dubrul, Gould and Wells by making the outer sheath stiffer than the inner sheath, as suggested by Williams, in order to enhance torqueability of the catheter.

Response to Arguments

16. Applicant's arguments with respect to claims 1-17 and 24-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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February 7, 2005